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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/814,114	03/22/2001	Michael L. Boyer II	8932-208-999	2083

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EXAMINER

HAMILTON, LALITA M

ART UNIT PAPER NUMBER

3624

DATE MAILED: 04/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	09/814,114	BOYER ET AL.	
	Examiner	Art Unit	
	Lalita M Hamilton	3764	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Summary

On October 7, 2002, an Office Action was sent to the Applicant rejecting claims 1-55. On February 7, 2003, the Applicant responded by amending claims 1 and 40-41 and canceling claim 55.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, 5-15, 17-22, 25-39, 41-43, 48-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyce, as set forth in the previous Office Action.

With regard to the amendments to claims 1 and 41, Boyce further discloses an opening defining an interior surface (col.6, lines 15-18) and the implant being formed of at least two different bones (col.4, lines 20-33).

Claims 3-4, 16, 23-24, 40, and 44-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyce in view of McIntyre (4,950,296), as set forth in the previous Office Action.

With regard to the amendment to claim 40, Boyce further discloses a core fit in an innermost of sheaths (fig.1).

Response to Arguments

Applicant's arguments filed February 7, 2003 have been fully considered but they are not persuasive. The Examiner has acknowledged the claim to priority under provisional application no.60/191,099 filed on March 22, 2000.

The Applicant has argued that Boyce does not disclose inner and outer sheaths, layers in fig.2 forming a sheath with an opening defining an interior surface, or at least two layers of bone components coupled together. In response, *Webster's II New Riverside University Dictionary* defines a sheath as "a covering ". Boyce discloses layers forming what the Examiner is interpreting as "sheaths" in that they provide a covering for layers in between (fig.2). Boyce further discloses a sheath having an opening defining an interior surface (fig.1 and col.6, lines 14-18) and at least two layers of bone components coupled together (col.4, lines 1-33).

The Applicant has argued that Boyce does not disclose an implant. In response, Boyce clearly discloses that the device is directed to bone-derived implants (col.1, line 65 to col.2, line 40).

The Applicant has argued that the previous Office Action fails to cite where Boyce discloses "a cross-section of the sheaths and core". In response, in the previous Office Action, the Examiner cited fig.1 earlier in the beginning of the 103 rejection; therefore, the Examiner did not again cite figure 1 next to this limitation. In fig.1, Boyce discloses what the Examiner has interpreted to be "a body formed from a cross-section of a core and a plurality of sheaths (fig.1 and col.5, lines 60-67).

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With regard to the McIntyre reference, the Applicant has argued that an implant having a plurality of sheaths formed of two different bones is not taught. In response, McIntyre discloses a sheath having a core (fig.1-4) and formed of cancellous bone and bone from the femur (col.2, line 57). The Examiner therefore found it to have been obvious to one having ordinary skill in the art to combine the Boyce and McIntyre references to demonstrate that using cancellous bone and bone from the femur as alternative choices of material for the bone is well known in the art.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lalita M Hamilton whose telephone number is (703) 306-5715. The examiner can normally be reached on Tuesday-Thursday (8:30-4:30).

The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746-6101 for regular communications and (703) 746-6101 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-2272.



LMH

April 17, 2003



**HANI M. KAZIMI
PRIMARY EXAMINER**